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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/695,848
Filing Date: October 29, 2003
Appellant(s): FEREK-PETRIC, BOZIDAR

Reed Duthler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 6, 2009 and June 5, 2009 appealing from the Office action mailed November 4, 2008.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 46-48, 50-52, 54-59, and 61-67 are rejected and pending.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the appellant's brief filed April 6, 2009 is correct except for the following: Claims 46 and 58 should each have been identified as "currently amended", "electrogram" should be present in line 13 of claim 46 and in line 15 of claim 58 and be striked through, and "electrocardiogram" should be underlined. Also, in line 11 of claim 46, "at least one" should be underlined. It appears that, in the Claims Appendix, Appellant has corrected the wording of claims 46 and 58 with regards to the use of "electrocardiogram" and not "electrogram" and with regards to the lack of "at least one" in line 11 of claim 46 in response to the Examiner's comments in the Advisory Action mailed March 10, 2009. The Examiner agrees with the corrections made by the Appellant in the Claims Appendix as filed on April 6, 2009.

(8) Evidence Relied Upon

6,733,485	WHITEHURST ET AL	5-2004
6,261,280	HOUBEN ET AL	7-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-48, 50-52, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al (U.S. Patent No. 6,733,485) in view of Houben et al (U.S. Patent No. 6,261,280). Whitehurst et al disclose a method of treating a cancerous tumor via a wholly-implantable medical device comprising a wholly-implantable electroporation device (150) which includes a drug reservoir (140) and operative control circuitry (145) both disposed within a housing (150). Whitehurst et al disclose implanting the wholly-implantable electroporation device (150) wholly within a body and delivering a drug to the body and proximate the tumor via a fluid conduit (141) coupled to the drug reservoir. Whitehurst et al also disclose delivering from the wholly-implantable electroporation device at least one electrical pulse across at least a portion of the cancerous tumor where the electric pulse produces an electric field from about 700 V/cm to about 1500 V/cm and has a pulse width of from about 50 ms to about 200 ms (lines 12-24 of column 8). In lines 37-62 of column 18, Whitehurst et al disclose sensing at least one biological parameter and providing a sense signal based on the biological parameter and conveying the biological parameter to the operative control circuitry, thus controlling the delivery of the at least one electrical pulse based on the sense signal. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value and a measurement of impedance across a portion of the cancerous tumor is used to determine if the electroporation procedure

needs to be continued (lines 37-49 of column 18 and lines 12-66 of column 19). In lines 36-47 of column 12, Whitehurst et al teach delivering the drug via an external drug delivery apparatus. Whitehurst et al disclose delivering the drug through a drug catheter (132). Whitehurst et al teach programming the electroporation device to deliver a particular therapy profile or algorithm which may occur after implantation (lines 24-49 of column 18).

Whitehurst et al disclose the method substantially as claimed. However, Whitehurst et al are silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Houben et al disclose a method for delivering stimulus or electrical pulses to generate an electric field and further teach detecting a qRs complex from an electrocardiogram during the delivery of the electrical pulses (lines 14-51 of column 4). Houben et al also teach synchronizing the delivery of the electrical pulses with the qRs complex (line 52 of column 4 to line 2 of column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Whitehurst et al with the steps of detecting a qRs complex from an electrocardiogram and synchronizing the delivery of the electrical pulses with the qRs complex as taught by Houben et al as both Whitehurst et al and Houben et al disclose implantable devices that delivery electrical pulses and Houben et al teach that it is well known to monitor a patient's heart such that the delivery of the electrical pulses can be synchronized with the qRs complex to reduce cardiac interference (see abstract and lines 20-49 of column 5).

Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al and Houben et al as applied to claim 46 above, and further in view of Sterzer (U.S. Patent No. 5,386,837). Whitehurst et al and Houben et al disclose the method substantially as claimed. However, Whitehurst et al and Houben et al are silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Whitehurst et al with the step of delivering a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Whitehurst et al are applied.

Claims 58, 59, 63-65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (U.S. Patent No. 5,389,069) in view of Sterzer and in view of Houben et al. Weaver discloses a method for treating a cancerous tumor comprising implanting a wholly-implantable electroporation device in a body, delivering a drug (40) to the body, and delivering at least one electrical pulse across a portion of the tumor.

Weaver also discloses the electroporation device as having at least one lead (20) with a therapy electrode (18) and delivering about one to about ten electrical pulses. Weaver discloses delivering electric pulses in the range of 100 volts to 1000 volts. Therefore, this is seen as delivering at least one electrical pulse producing an electric field strength of about 700 volts/cm to 1500 volts/cm as the actual electric field strength would be dependent on the relative location of the first and second electrode and of the size and location of the tumor being treated. Weaver also discloses delivering at least one electrical pulse of about 100 microseconds to about 1000 microseconds. The drug (40) is delivered via an external drug apparatus (42). In Figure 2, Weaver shows a drug catheter (54) coupled to a housing (62) of the electroporation device. Weaver teaches programming the electroporation device which may occur after implantation (lines 23-53 of column 4).

Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of delivering a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better

delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Weaver are applied. As to claim 59, Sterzer discloses a controlled rise of the temperature of the tumor and also allowing for a high therapeutic temperature which is below a safe temperature. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that by increasing the temperature of the tumor by applying the high frequency stimulus as taught by Sterzer would require sensing the temperature such that the temperature of the treated tumor can be kept at a safe level.

Additionally, Weaver is silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Houben et al disclose a method for delivering stimulus or electrical pulses to generate an electric field and further teach detecting a qRs complex from an electrocardiogram during the delivery of the electrical pulses (lines 14-51 of column 4). Houben et al also teach synchronizing the delivery of the electrical pulses with the qRs complex (line 52 of column 4 to line 2 of column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the steps of detecting a qRs complex from an electrocardiogram and synchronizing the delivery of the electrical pulses with the qRs complex as taught by Houben et al as both Weaver and Houben et al disclose implantable devices that delivery electrical pulses and Houben et al teach that it is well known to monitor a patient's heart such that the delivery of the electrical pulses can be synchronized with

the qRs complex to reduce cardiac interference (see abstract and lines 20-49 of column 5).

Claims 61, 62, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer and in view of Houben et al as applied to claim 58 above, and further in view of Whitehurst et al. Weaver in view of Sterzer and in view of Houben et al disclose the method substantially as claimed. However, Weaver, Sterzer, and Houben et al are silent to the step of measuring impedance across a portion of the tumor and comparing the impedance to a threshold impedance value and to the specifics of the cancerous tumor being an osteosarcoma. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value (lines 37-49 of column 18 and lines 12-66 of column 19). Also, in lines 57-67 of column 8, Whitehurst et al teach treating an osteosarcoma or bone sarcoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of measuring the impedance of the tumor as taught by Whitehurst et al as Whitehurst et al teach that it is well known to use a measurement of impedance across a portion of the cancerous tumor to determine if the electroporation procedure needs to be continued. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Weaver to treat an osteosarcoma as taught by Whitehurst et al as

both Weaver and Whitehurst et al teach using electroporation to treat cancerous tumors which can include osteosarcomas.

(10) Response to Argument

Appellant's arguments on pages 6-9 of the Appeal Brief filed June 5, 2009 with regards to the rejections of claims 46-48, 50-52, 54-59, and 61-67 are not persuasive.

a. Appellant's arguments in lines 5-12 of page 6 are not persuasive as the Examiner disagrees with the Appellant's reading of Houben et al as teaching that synchronization is provided to enable the sensing of the signals (qRs complexes) from the tissue (heart) produced in response to the applied treatment pulse. Houben et al do not teach that the qRs signal or complex is produced in response to the applied electrical stimulus or pulse. Houben et al disclose that the qRs signal or complex is obtained from the output of the heart monitor (40) (line 14 of column 4 to line 2 of column 5, lines 40-56 of column 5, and lines 1-4 of column 8). Furthermore, Houben et al disclose detecting the qRs signal or complex and synchronizing the electrical field stimulus or pulse delivered to the pancreas with the qRs signal so that the delivery of the electrical field is not coincident with the qRs signal (lines 29-56 of column 5).

b. Appellant's arguments in lines 13-22 of page 6 are not persuasive. Appellant's arguments regarding the heart being treated by Houben et al are rebutted as Houben et al teach treating the pancreas with electrical pulses and do not teach that the heart is treated. Applicant's arguments that the tumor tissue treated by the device of Whitehurst et al does not generate electrical signals to which treatment pulses can be synchronized or which are generated in response to the application of the treatment

signals are not persuasive as the claims are not drawn to synchronizing the electrical pulse with generated electrical signals or generating electrical signals in response to the application of the treatment signals. Both Whitehurst et al and Houben et al disclose treating a patient by delivering an electrical pulse to the patient. Houben et al disclose that it is well known to monitor cardiac activity when delivering an electrical pulse where the qRs from an electrocardiogram is detected and the delivery of the electrical pulse is synchronized with the qRs signal (see abstract, lines 42-61 of column 2, and line 52 of column 4 to line 2 of column 6). Houben et al further teach synchronizing the delivery of the electrical pulse with the qRs signal so that the delivery of the electrical pulse to the pancreas is not coincident with the qRs signal (lines 29-56 of column 5). Therefore, it would be obvious to add the qRs synchronization of Houben et al to the method of Whitehurst et al as both Whitehurst et al and Houben et al teach delivering an electrical pulse to a patient and Houben et al teach that it is well known to monitor a patient's heart such that the delivery of the electrical pulses can be synchronized with the qRs complex to reduce cardiac interference (see abstract and lines 20-49 of column 5).

c. As to Appellant's arguments in line 23-25 of page 6, the teachings of Whitehurst et al have not been used to disclose the timing of the delivery of the treatment pulse being synchronized to any particular event or parameter.

d. As to Appellant's arguments in lines 1-28 of page 7 are not persuasive, the teachings of Whitehurst et al have not been used to disclose synchronizing the delivery of the electrical pulses with the various parameters that are sensed as disclosed in line 61 of column 17 to line 62 of column 18 of Whitehurst et al. However, Houben et al do

disclose synchronizing the delivery of the electrical pulses with the qRs complex or signal to reduce cardiac interference (see abstract and lines 20-49 of column 5).

e. Appellant's arguments in lines 1-6 of page 8 are not persuasive as the Examiner disagrees that Whitehurst et al in view of Houben et al are deficient and fail to disclose the claimed invention.

f. Appellant's arguments in lines 7-23 of page 8 are not persuasive. The teachings of Weaver have not been used to disclose synchronizing the delivery of the electrical pulses with the qRs signals or complexes. However, Houben et al do disclose synchronizing the delivery of the electrical pulses with the qRs complex or signal to reduce cardiac interference (see abstract and lines 20-49 of column 5). Therefore, Weaver in view of Sterzer and in view of Houben et al do disclose the claimed invention.

g. Appellant's arguments in lines 1-8 of page 9 are not persuasive as the Examiner disagrees that Weaver in view of Sterzer and in view of Houben et al are deficient and fail to disclose the claimed invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Bhisma Mehta/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Michael Phillips/

RQAS